ENGLISH

# Orthopantomograph® OP30

## Digital Panoramic X-ray Unit

# User's Manual

Number 204403 ver. 4 (2010-03)

Copyright

Document code: 204403 ver. 4 (2010-03)
Copyright © 2009 by PaloDEx Group Oy.
All rights reserved.

Documentation, trademark and the software are copyrighted with all rights reserved. Under the copyright laws the documentation may not be copied, photocopied, reproduced, translated, or reduced to any electronic medium or machine readable form in whole or part, without the prior written permission of Instrumentarium Dental.

The original language of this manual is English.

Instrumentarium Dental reserves the right to make changes in specification and features shown herein, or discontinue the product described at any time without notice or obligation. Contact your Instrumentarium Dental representative for the most current information.

CE
0537

Manufactured by

Instrumentarium Dental
Nahkelantie 160 (P.O. Box 20)
FI-04300 Tuusula
FINLAND
Tel. +358 (0)10 270 2000
Fax. +358 9 851 4048

For service, contact your local distributor.

# Contents

**1. Introduction ..... 1**
1.1 Orthopantomograph® OP30 X-ray unit ..... 1
1.2 About this manual ..... 1
**2. Unit description ..... 2**
2.1 Main parts ..... 2
2.2 Unit controls ..... 4
2.3 Accessories ..... 5
**3. Using the Unit ..... 6**
3.1 Preparing the Unit ..... 6
3.2 Taking Exposures ..... 7
Panoramic adult, child and bitewing ..... 7
Temporomandibular Joint (TMJ) ..... 15
**4. Operating the unit without x-rays ..... 21**
**5. Unit settings ..... 22**
5.1 Opening the Setup window ..... 22
5.2 The Device page ..... 23
Status field ..... 23
Retrieve Last Image field ..... 23
Device Serial Number field ..... 24
**6. Troubleshooting and Maintenance ..... 25**
6.1 Error messages and symbols ..... 25
Error symbols ..... 26
User errors ..... 26
System errors ..... 27
6.2 Care and Maintenance ..... 28
Cleaning and disinfecting the unit ..... 28
*Surfaces ..... 28*
*Positioning mirror and light lenses ..... 28*
*Surfaces that the patient touches ..... 28*
Correct operation of the unit ..... 28
Yearly maintenance ..... 29
**7. Warnings and precautions ..... 30**
**8. Disposal ..... 32**
**Appendix A. Technical Information ..... A-1**

# 1. Introduction

## 1.1 Orthopantomograph® OP30 X-ray unit

The **Orthopantomograph® OP30** (the unit) is a digital panoramic dental x-ray unit designed to take:

- adult panoramic exposures,
- child panoramic exposures (reduced width)
- bitewing exposures
- and TMJ exposures.

The unit uses a CCD sensor as the image receptor and a PC with suitable (MDD approved) dental imaging software, such as Cliniview, for image acquisition and handling.

**IMPORTANT NOTE:**
Before using the unit for the first time, make sure that it is set up to your requirements. See section **5. Unit Set up**.

**USA only**
**Caution:**
Federal law restricts this device to sale by or on the order of a dentist or other qualified professional.

## 1.2 About this manual

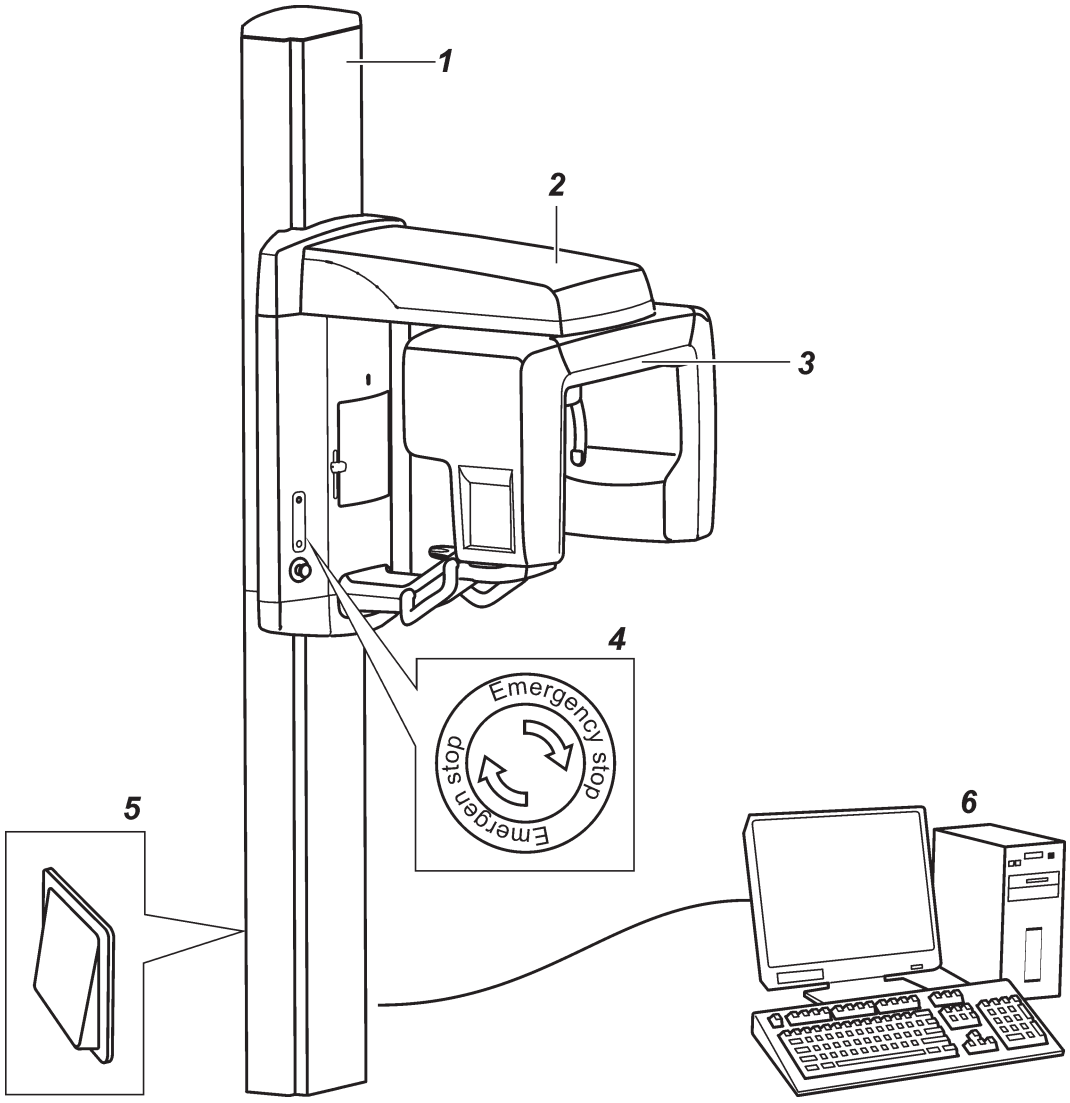
This manual describes how to use and set up the unit.

Please read these instructions carefully **before** operating the unit.

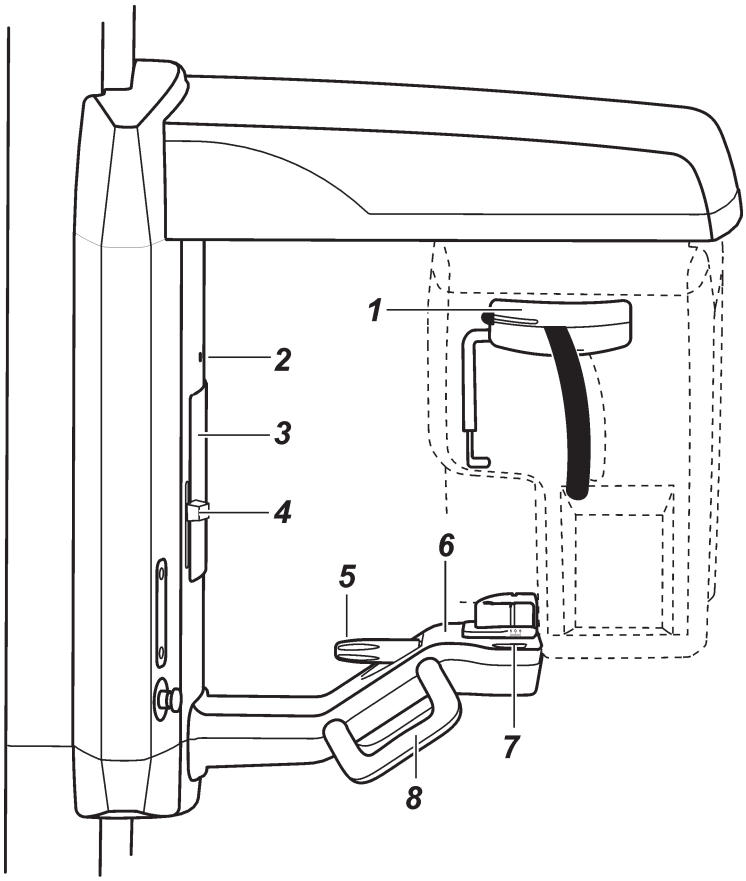
Before operating this unit read and observe the warnings and precautions that appear in section **7. Warnings and Precautions**.

# 2. Unit description

## 2.1 Main parts

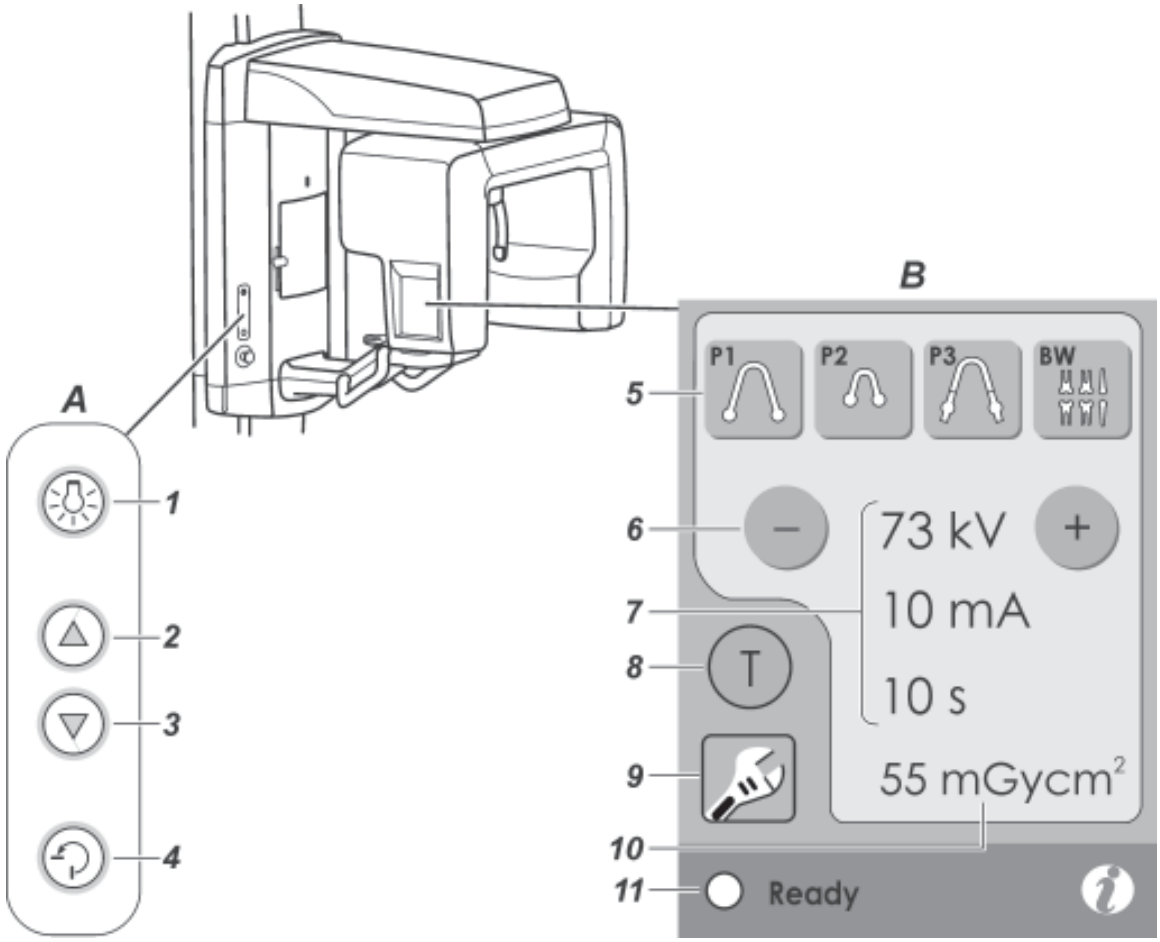



1 Column
2 Upper shelf
3 Rotating unit
4 **Emergency stop button** - Press to stop, rotate to release.
5 On / off switch (rear of column)
6 **PC** with MDD approved dental imaging software




1 Head support
2 Midsaggital light
3 Mirror
4 Frankfort light and light positioning knob
5 Focal trough positioning knob
6 Patient support
7 Focal trough light
8 Patient support handles

## 2.2 Unit controls



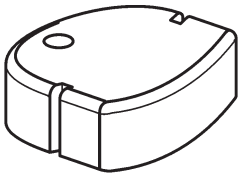

**A. Side control panel**

1 Lights key - switches the patient positioning lights on and off
2 Up key - drives the unit up
3 Down key - drives the unit down
4 Return key - drive the unit to the patient in/out position (PIO)

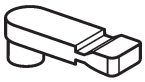
**B. Main control panel**

5 Program selection keys - P1 = adult pan, P2 = child pan, P3 = TMJ, BW = bitewing
6 kV selection keys
7 Exposure values
8 Test key - operated the unit without x-rays
9 Service key
10 Dose Area Product (DAP)
11 Ready indicator light - unit ready for an exposure

## 2.3 Accessories

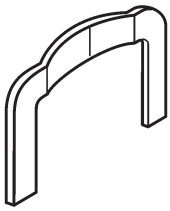


Chin rest

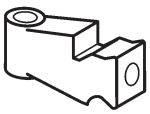


Bite block

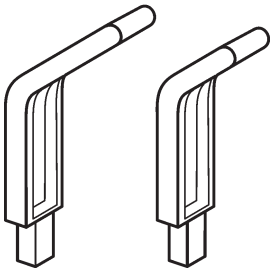
Bite fork 71 mm



Chin support



Edentulous bite positioner



Nose support long - for children
Nose support short - for adults

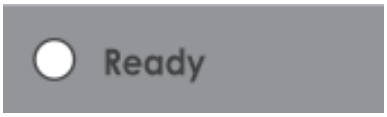
# 3. Using the Unit

**IMPORTANT NOTE:**
If the unit is being used for the first time or if you are using the unit for the first time check that it is set up to your requirements. See section **5. Unit Set up**.

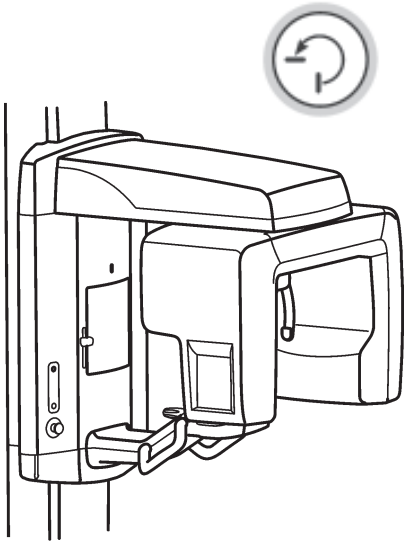
## 3.1 Preparing the Unit

1. **PC:** Switch on the PC that is connected to the unit.

2. **PC:** Open the dental imaging software you are using and enable image capture.
   Refer to the instructions supplied with the dental imaging software for information on how to do this.



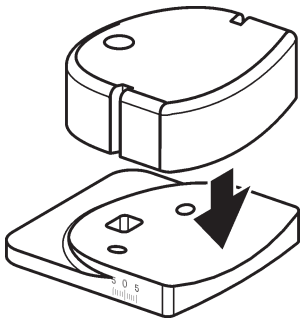

3. Switch the unit on. The on/off switch is at the base of the column at the rear.
   The unit display will come on and the unit will carry out a self test. When the Ready light turns GREEN the unit is ready to take an exposure.



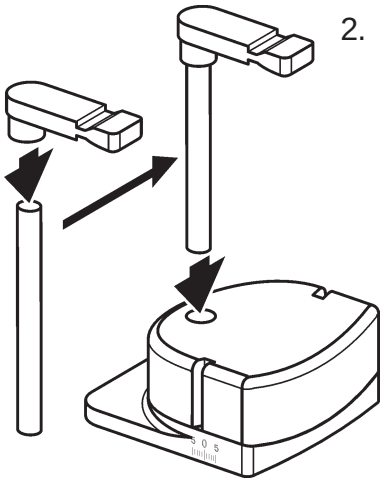
4. Press the **Return** key to drive the rotating unit to the **P**atient **I**n/**O**ut (PIO) position.

## 3.2 Taking Exposures

### Panoramic adult, child and bitewing

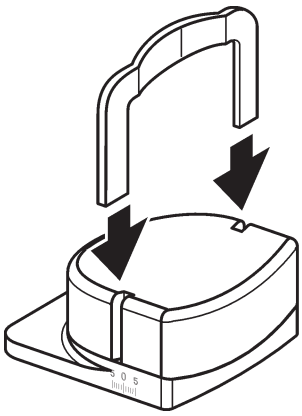


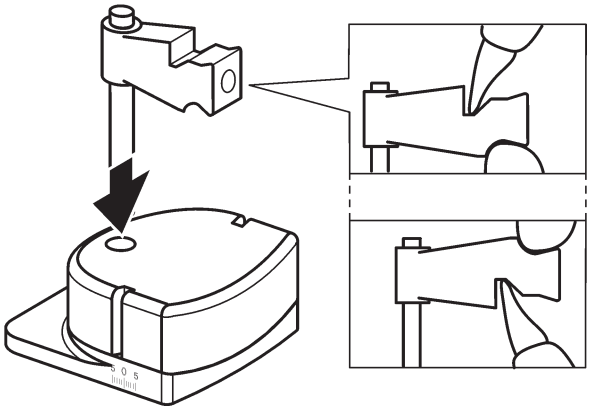
1. Slide the chin rest on to the support holder.



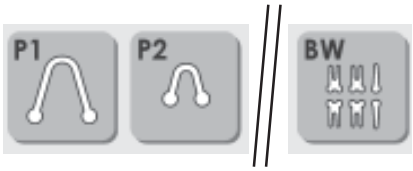
2. **Dentate patients**. Attach the bite block to the bite fork and then insert the bite fork and bite block into the hole in the chin rest.

**Edentulous patients**. Attach the chin support to the chin rest. If the patient is **partially edentulous** attach the edentulous bite positioner to a bite fork and then insert the bite fork and edentulous bite positioner into the hole in the chin rest.





3. Place the appropriate disposable covers on to the patient support you are using.




4. Press the program key to select the panoramic program you require, **adult (P1)**, **child (P2)** or **bitewing (BW)**.
The magnification for these programs is 1.25.

5. Use the **+** / **-** keys to select the required kV for the patient being examined:

- child

- juvenile

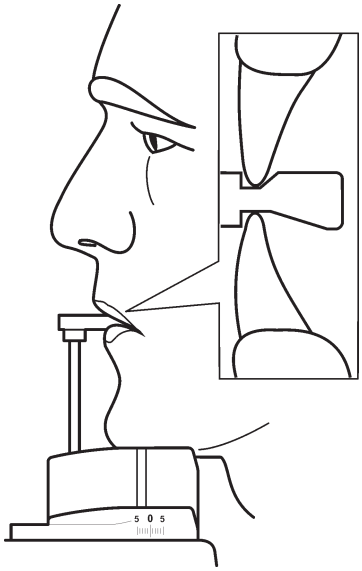
- adult

- large adult

The DAP value will appear on the display.

6. Ask the patient to remove any spectacles, dentures, jewellery and hair clips and pins.
Place a protective lead apron over the patient's shoulders.
**NOTE:**
If the patient is nervous, you can reassure them by demonstrating how the unit works before taking the exposure. See section **4. Operating the unit without x-rays**.

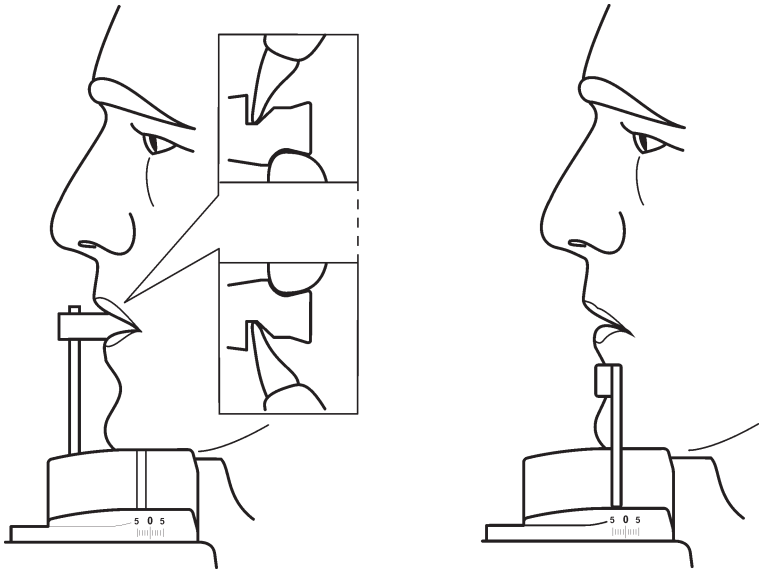
7. Press the **Up/Down** keys to adjust the height of the chin rest so it is slightly higher than the patient's chin so that the patient will have to stretch up to place their chin on the chin rest.



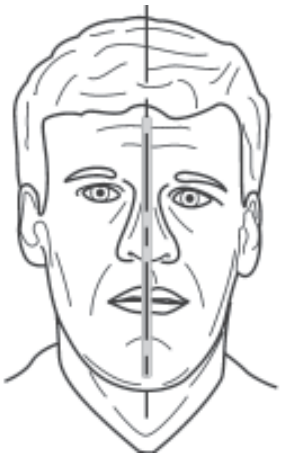
8. If the patient is dentate ask the patient to step into the unit, grasp the patient handles, place his/her chin on the chin rest and bite the notches in the bite block.

   If the patient is partially edentoulous ask the patient to bite the edentulous bite positioner.

   If the patient is edentulous ask the patient press chin against the chin support.

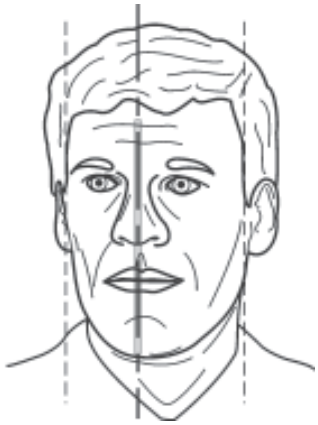


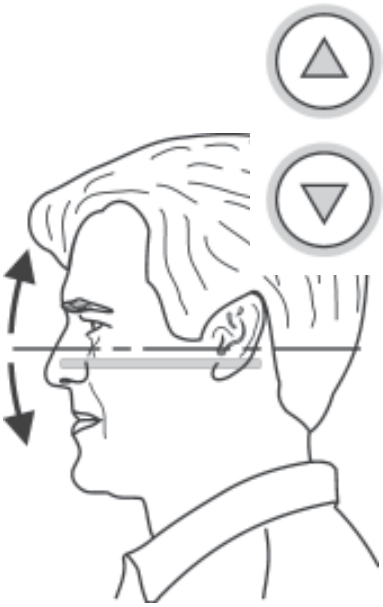
9. Press the Lights key to switch the patient positioning lights on. They will remain on for two minutes.
   **NOTE:**
   The patient positioning lights will automatically come on when either the **Up** or **Down** key is pressed.



10. Look at the reflection of the patient in the mirror and position the **midsagittal plane** of the patient so that it coincides with the midsagittal plane light.

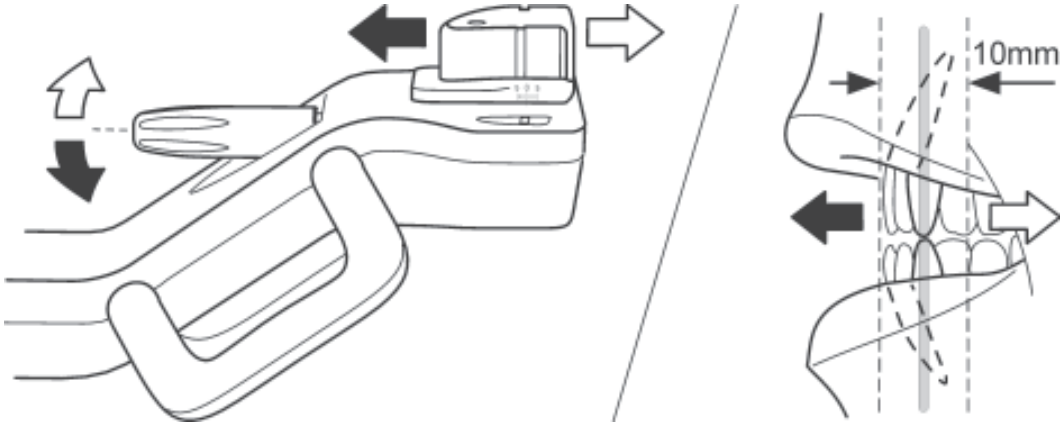
    Make sure that the patient is looking straight ahead and that the patient's head is not tilted or turned to one side.





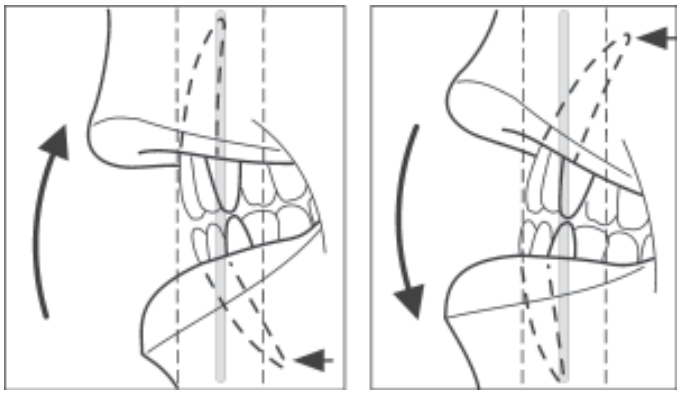
11. Press either **Up/Down** key to adjust the tilt of the patient's head until the patient's **Frankfort plane** coincides with, or is parallel to, the horizontal light.
    **CAUTION**:
    When pressing the **Up/Down** keys to adjust the tilt of the patient's head take care not to cause the patient any distress or discomfort.

12. The focal trough light indicates the center of the focal trough which is 10 mm wide at the front. Ask the patient to open their lips so that you can see the patient's teeth.
For **adult (P1)** and **child (P2)** panoramic exposures use the focal trough knob to position the patient so that the focal trought light is in the center of the patient's upper and lower third teeth (canines).

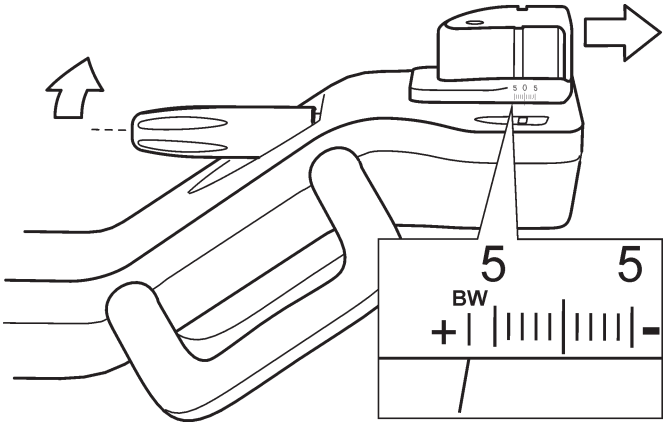


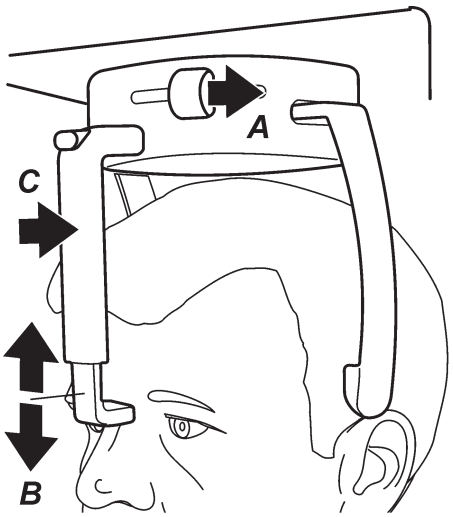

The roots of the upper and lower front incisors must be located within the focal trough and be on the same vertical plane.

If the roots of the upper and lower front incisors are not on the same vertical plane adjust the tilt of the patient's head until they are.



For **bitewing (BW)** panoramic exposures position the chinrest on the BW line.

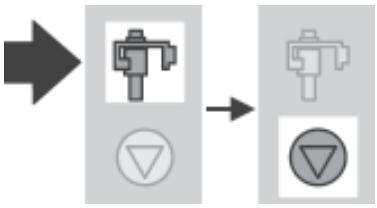



13. Close the temple supports by sliding the temple support knob to the right (A). Make sure that patient's neck is stretched and straight.
Adjust the position of the nasion support (B) and then carefully push the forehead support in until it touches the patient's nasion (C).

14. Ask the patient to press their lips together and press their tongue against the roof of their mouth. Then ask the patient to look at a fixed point in the mirror and to remain still for the duration of the exposure.
The exposure takes approximately ten seconds.

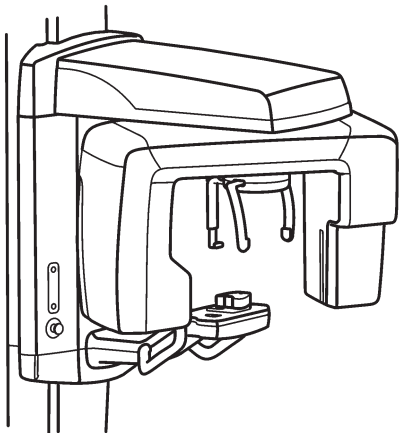
15. Ask the patient to step forward slightly so that they out of balance and “hanging” onto the support handles. This will force the patient to stretch their neck as far a possible.
    Check that the patient has not moved and is still in the correct position.

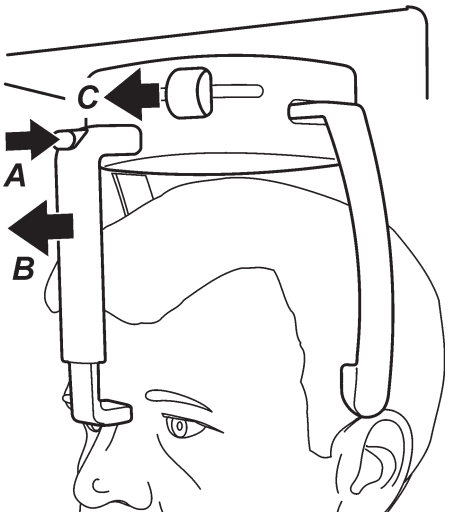


16. **PC:** Enable image capture.

17. Move at least two metres away from the unit and protect yourself from radiation.
    Make sure that you can see and hear the patient during the exposure.

18. Press and hold down the exposure button for the duration of the exposure. During the exposure you will hear an audible signal and the exposure warning indicator on the control panel will come on. The rotating unit will rotate around the patient’s head and then stop. When the rotating unit stops, the exposure has been taken.



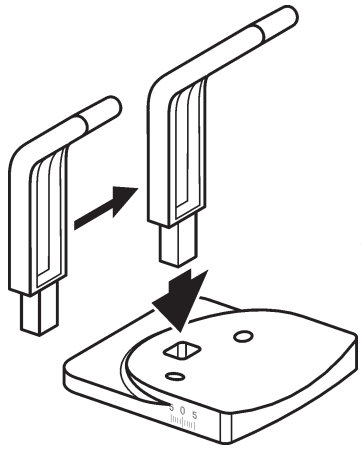



19. Press the release button at the top of the forehead support (A) and then slide the forehead support away from the patient (B). Open the temple supports by sliding the temple support knob to the left (C). Guide the patient out of the unit.

20. Press the **Return** key to drive the unit to the PIO position.
    **NOTE:**
    After the exposure, a timer indicating the tubehead cooling time will appear on the display. A new exposure cannot be taken until the counter reaches zero, the exposure time reappears on the display, and the ready light comes on.

21. **PC:** After the exposure has been taken a progress bar will appear. This indicates that the image is being transfered to the PC.

## Temporomandibular Joint (TMJ)



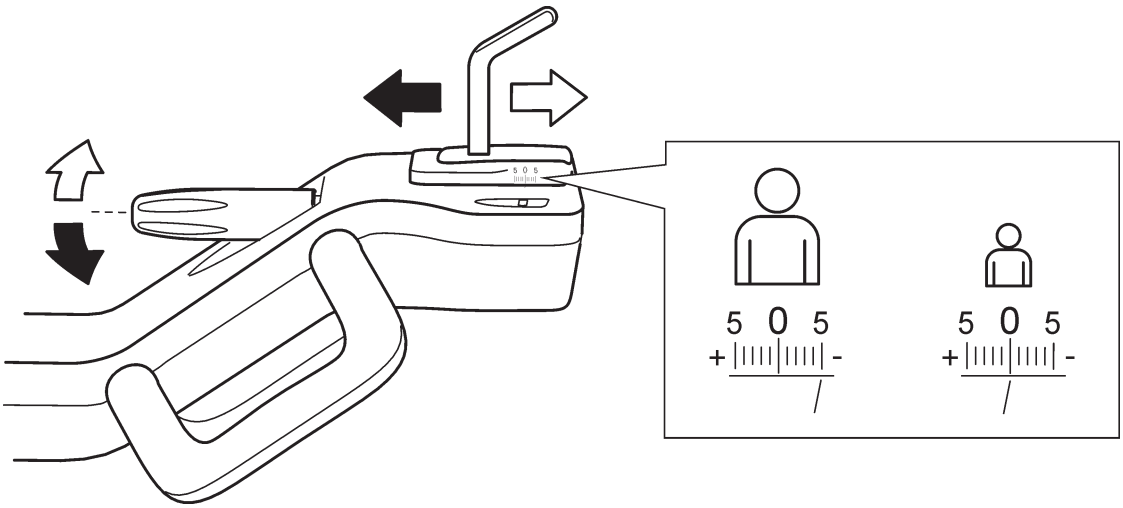
1. Slide the nose support into the support holder. Use the short version for adults and the long version for children.

2. Place a disposable cover on to the nose support.

3. Press the **TMJ** key (P3) to select TMJ program. The magnification is 1.25.

4. Select the same **kV** values (or higher) as the Panoramic program.

5. Use the focal trough knob and position the support holder so that it is -5 for an adult and 0 for a child.



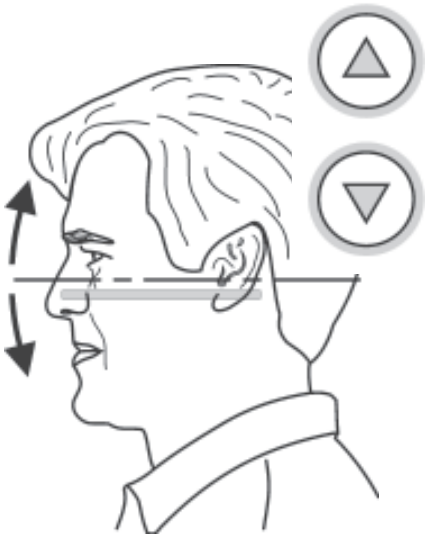
6. Ask the patient to remove any spectacles, false teeth, jewellery and hair clips and pins. Place a protective lead apron over the patient's shoulders.
**NOTE:**
If the patient is nervous you can reassure them by demonstrating how the unit works before taking the exposure. See section **4. Operating the unit without x-rays**.

6. Press the **Up/Down** keys to adjust the height of the nose support so that the top is level with the patient's upper lip.

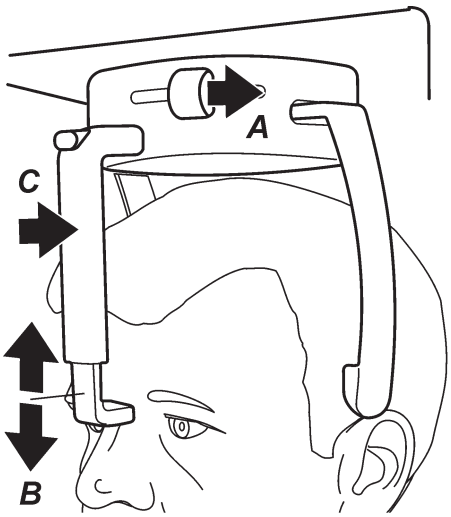
7. Ask the patient to step into the unit, grasp the patient handles and press their top lip against the top of the nose support.

8. Press the Lights key to switch the patient positioning lights on. They will remain on for two minutes.
**NOTE:**
The patient positioning lights will automatically come on when either the **Up** or **Down** key is pressed.

9. Look at the reflection of the patient in the mirror and position the **midsagittal plane** of the patient so that it coincides with the midsagittal plane light. Make sure that the patient is looking straight ahead and that the patient's head is not tilted or turned to one side.



10. Press either **Up/Down** key to adjust the tilt of the patient's head until the patient's **Frankfort plane** coincides with, or is parallel to, the horizontal light.
**CAUTION:**
When pressing the **Up/Down** keys to adjust the tilt of the patient's head take care not to cause the patient any distress or discomfort.



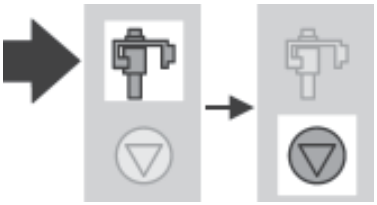

11. Close the temple supports by sliding the temple support knob to the right (A). Make sure that patient's neck is stretched and straight.
Adjust the position of the nasion support (B) and then carefully push the forehead support in until it touches the patient's nasion (C).

12. Check once more that the patient is positioned correctly and has not moved.

13. If you are taking a TMJ exposure with the patient's **mouth closed** ask the patient to clench their back teeth together, look at a fixed point in the mirror and to remain still for the duration of the exposure.

If you are taking a TMJ exposure with the patient's **mouth open**, ask the patient to open their mouth, look at a fixed point in the mirror and to remain still for the duration of the exposure.

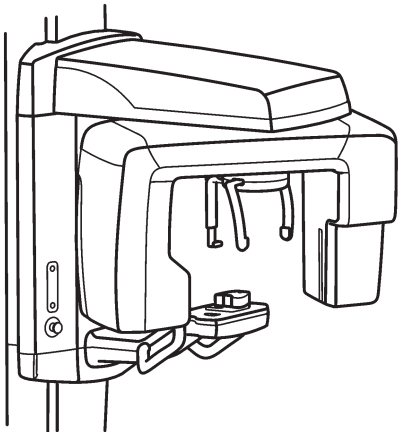
The exposure takes approximately ten seconds.



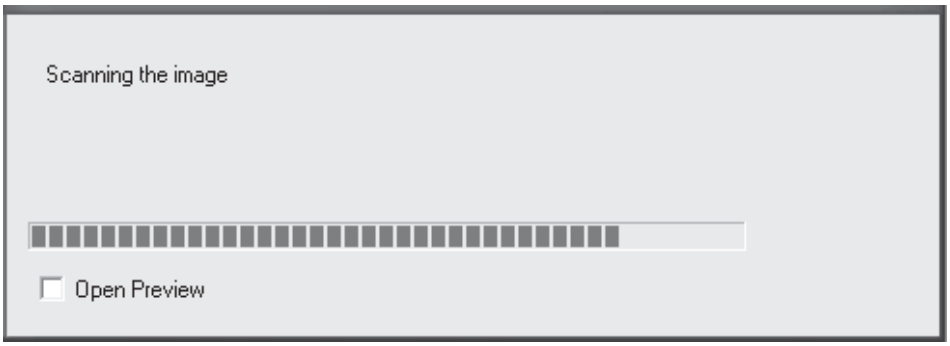
14. **PC:** Enable image capture.

15. Move at least two metres from the unit and protect yourself from radiation. Make sure that you can see and hear the patient during the exposure.

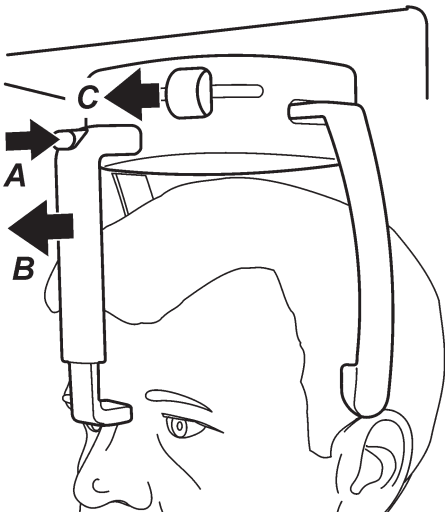
16. Press and hold down the exposure button for the duration of the exposure. During the exposure you will hear an audible signal and the exposure warning indicator on the control panel will come on. The rotating unit will rotate around the patient's head and then stop. When the rotating unit stops, the exposure has been taken.



17. **PC:** After the exposure has been taken a progress bar will appear. This indicates that the image is being transfered to the PC.



18. If you wish to take a second TMJ exposure, press the **Return** key to drive the unit back to the PIO position, enable image capture (**PC**) and then reposition the patient and take the second exposure steps 13 -15.




19. Press the release button at the top of the forehead support (A) and then slide the forehead support away from the patient (B). Open the temple supports by sliding the temple support knob to the left (C). Guide the patient out of the unit.

20. Press the **Return** key to drive the unit to the PIO position.

# 4. Operating the unit without x-rays

In some situations, for example with nervous patients or patients with unusual anatomy, you may wish to operate the unit without x-rays before taking an exposure.

Press the **T** key (Test), the display will clear. The exposure switch can now be pressed to demonstrate how the unit operates without x-rays being generated.

Press the **T** key a second time to return to the normal exposure mode.

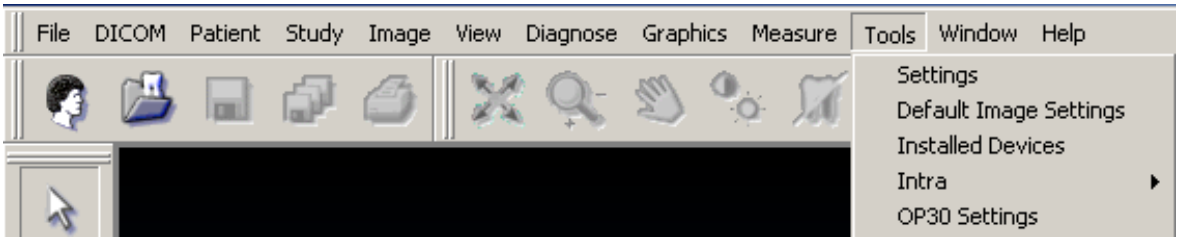
**NOTE:**
After switching the unit off and then on again the unit returns to the normal (non test) mode.

# 5. Unit settings

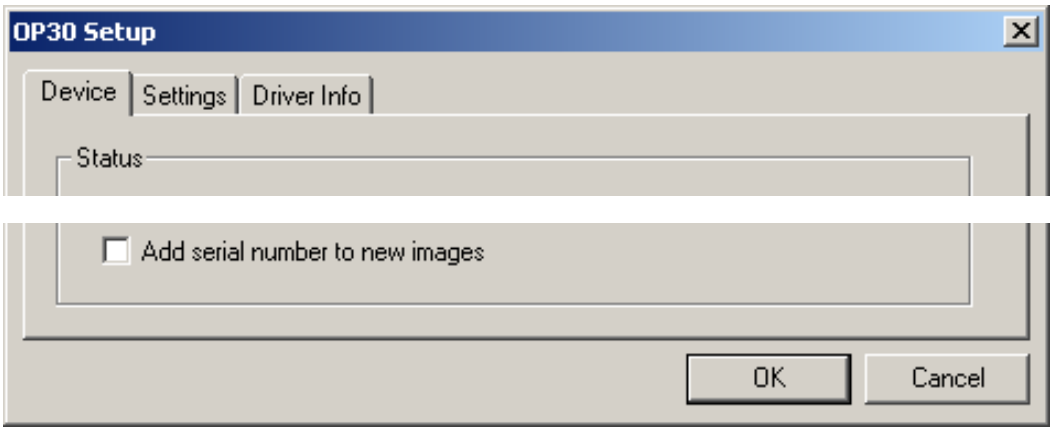
## 5.1 Opening the Setup window

1. **PC:** Open Cliniview or the dental imaging software you are using.

2. Select **Tools** and then click **OP30 Settings**.

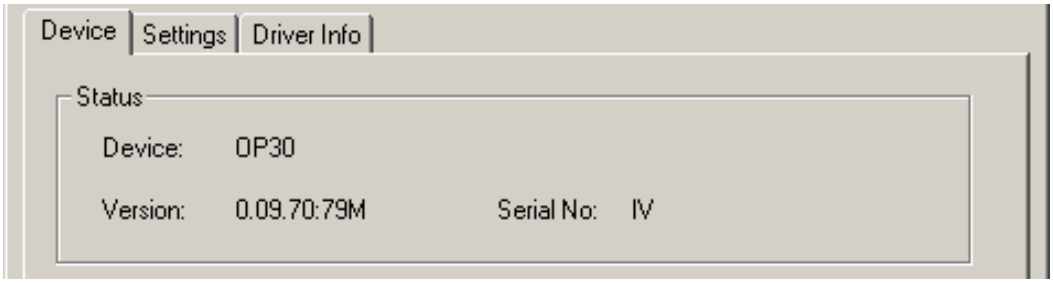



3. The **OP30 Setup** window will appear.



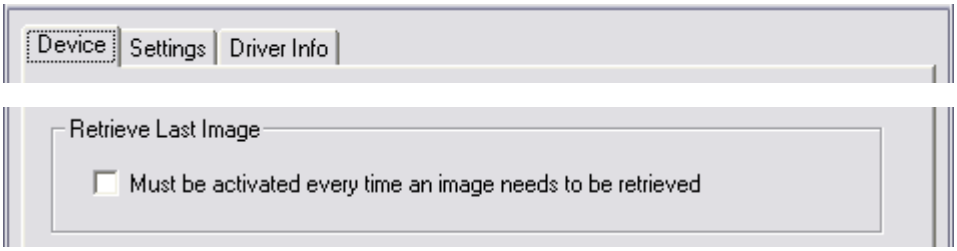
## 5.2 The Device page

### **Status** field




**Device** indicates whether the unit is connected to the PC. **Version:** shows the software version of the unit and **Serial No:** the serial number of the unit.

### **Retrieve Last Image** field




If the last image read is not transferred to the PC because of a network, PC or software failure, the image can be retrieved from the unit memory.

**IMPORTANT NOTE**
The last read image can only be retrieved if the unit is left on after the last exposure was taken. If the unit is switched off the image will be lost.

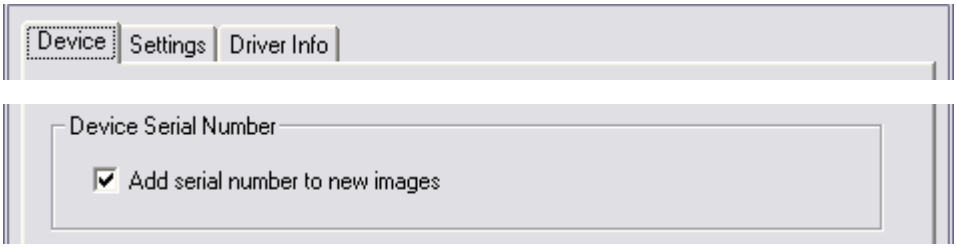
To retrieve the last image:

**A**. Correct the problem that caused the network, PC or software failure, and then reopen the patient card.

**B**. The last scanned image should automatically be transferred.
If it is not, click the check box in the **Retrieve Last Image** field to retrieve the last image taken by the unit.

**C**. Click **OK** to close the **OP 30 Setup** window. The last image taken will appear on the patient card.

### **Device Serial Number** field




Click the **Add serial number ...** check box and the serial number of the unit will be added to all new images. The serial number will appear in the top left-hand corner and the bottom right-hand corner of the image.

# 6. Troubleshooting and Maintenance

## 6.1 Error messages and symbols

If the unit is not used correctly or the unit malfunctions an error message or symbol will appear on the unit display.

There are three groups of error message:

- **Error symbols**
  The symbol will clear when the problem is corrected.

- **H**, user errors

- **E** (Error), exposure errors, these occur during exposure.
  These appear on the error message display.
  Touch the **CLEAR** button to clear the error message and return to the main display.
  **NOTE:**
  If the CLEAR button does not appear on the error message display you will have to wait for the error to clear automatically.

## Error symbols

REASON
i. The PC connected to the unit is not on.
ii. The dental imaging software in the PC is not open.
iii. The cable connecting the unit to the PC is disconnected or damaged.

SOLUTION
i. Switch the PC on.
ii. Open the dental imaging software and select a patient.
iii. Reconnect the cable. If damaged, contact service.

REASON
The emergency stop button is pressed down in the STOP position.

SOLUTION
Rotate and release the emergency stop button. The error symbol will clear.

## User errors

**H1**

REASON
The exposure button was released during an exposure.

SOLUTION
Clear the error message and check if the attempted exposure is sufficient for the diagnostic task. If it is not, take a new exposure.
If the exposure failed while the exposure button was still being pressed, check the exposure switch by taking a test exposure without patient to see if the exposure button is defective or not. If the same problem occurs again, contact service.

## System errors

**E4**

REASON
Tubehead too hot or too cold.

SOLUTION
When the error message automatically clears the tubehead has reached the correct operating temperature. In normal conditions this will take about 30 minutes for the tubehead to reach the correct temperature. If the error message does not disappear within a reasonable amout of time, contact service.

**E5**

REASON
Line voltage not within limits.

SOLUTION
If the error message reappears it indicates that the voltage is not within limits. The error message will automatically clear when the voltage returns to then correct level. If the error message keeps on appearing or does not disappear within a reasonable amout of time, contact service.

**E19**

REASON
Exposure switch stuck down during unit start.

SOLUTION
Switch the unit off and check that the exposure switch is not stuck in the exposure position. Switch the unit on again. If the message reappears, contact service.

**Exx** (all other E errors except **E4, E5** and **E19** (above).

SOLUTION
Clear the error message and try to take an exposure **without a patient**. If the error message reappears, switch the unit off, wait for half a minute and then switch the unit on again. If the error message reappears contact service.

## 6.2 Care and Maintenance

### Cleaning and disinfecting the unit

**Warning**
Switch the unit off before cleaning it.

***Surfaces***

All surfaces can be wiped clean with a soft cloth dampened with a mild detergent. DO NOT use abrasive cleaning agents or polishes on this equipment.

***Positioning mirror and light lenses***

The positioning mirror and positioning light lenses are made of glass. Use a soft cloth dampened with a mild detergent. NEVER use abrasive cleaning agents or polishes on these parts.

***Surfaces that the patient touches***

All surfaces and parts that the patient touches or comes into contact with must be disinfected after each patient. Use a disinfectant that is formulated specifically for disinfecting dental equipment and use the disinfectant in accordance with the manufacturer's instructions.

### Correct operation of the unit

If any of the unit's controls, displays or functions fail to operate or do not operate in the way described in this manual, switch the unit off, wait 30 seconds and then switch the unit on again. If the unit still does not operate correctly contact your service technician for help.

If you hear the exposure warning tone but the exposure warning light on the display does not come on when an exposure is taken, stop using the unit and contact your service technician for help.

If you do not hear the exposure warning tone when an exposure is taken, stop using the unit and contact your service technician for help.

Every week check that the power supply cable is in good order (not damaged in any way) and that the unit operates correctly in accordance with the instructions in this manual.
Make sure that the unit cannot be driven up/down when the emergency stop button has been pressed down.

## Yearly maintenance

Once a year an authorized service technician must carry out a full inspection of the unit. During the inspection the following tests will be carried out:
– a kV/mA test
– a beam alignment test
– a check that the safety ground is connected
– a check that the positioning lights operate
– a check that oil is not leaking from the tube head
– a check that all covers and mechanical parts are correctly secured and have not come loose.
A full description of all the tests and checks is described in the Service Manual.

# 7. Warnings and precautions

- The unit must only be used to take the dental x-ray exposures described in this manual. The unit must NOT be used to take any other x-ray exposures. It is not safe to use the unit to take an x-ray exposure that the unit is not designed to take.
- If this device will be used with 3rd party imaging application software not supplied by PaloDEx, the 3rd party imaging application software must comply with all local laws on patient information software. This includes, for example, the Medical Device Directive 93/42/EEC and/or FDA if applicable.
- Do not connect any device to the unit that has not been supplied with the unit or that is not recommended by PaloDEx.
- The unit or its parts must not be changed or modified in any way without approval and instructions from PaloDEx.
- The unit may be dangerous to the user and the patient, if the safety regulations in this manual are ignored, if the unit is not used in the way described in this manual and/or if the user does not know how to use the unit.
- Because the x-ray limitations and safety regulations change from time to time, it is the responsibility of the user to make sure that all the valid safety regulations are fulfilled.
- It is the responsibility of the doctor to decide if the x-ray exposure is necessary.
- Always use the lowest suitable x-ray dose to obtain the desired level of image quality.
- Avoid taking x-ray exposures of pregnant women.

- If the patient is using a pacemaker, consult the manufactuer of the pacemaker to confirm that the x-ray unit will not interfer with the operation of the pacemaker before taking an exposure.
- The user of the unit must stand at least two meters away from the unit AND protect him/herself from radiation when taking exposures. It is recommended that a moveable radiation protection screen be used.
- The user must be able to see and hear the patient during an exposure.
- The user must see the exposure warning light and/ or hear the audio exposure warning signal during the exposure. If the unit is installed in such a place where the exposure warning light cannot be seen, a separate exposure warning light should be used. Please contact you local service for help.
- Disinfect all the surfaces that the patient is in contact with after every patient.
- If the unit does not appear to be working correctly, switch the unit off and release the patient. Make sure that the unit operates correctly before you continue using it. If you are not sure whether the unit is operating correctly, please contact your local service for help.
- If the unit will not be used for a long time, switch the unit off in order to prevent unauthorized people using the unit.
- The unit should not be used adjacent to or stacked with other equipment.
- This unit can interfere with other devices due to its EMC characteristics and other devices can interfere with this unit due to their EMC characteristics. Refer to the EMC Declaration (A4) in Appendix A for more information.

# 8. Disposal

At the end of useful service life of the device, its spare parts, its replacement parts and its accessories make sure that you follow all local, national and international regulations regarding the correct and safe disposal and/or recycling of the device, its spare parts, its replacement parts and its accessories.

The device, its spare parts, its replacement parts and its accessories may include parts that are made of or include materials that are non-environmentally friendly or hazardous. These parts must be disposed of in accordance with all local, national and international regulations regarding the disposal of non-environmentally friendly or hazardous materials.

Hazardous materials and parts that are made of or contain these materials:

LEAD:
Tubehead housing, collimator, CCD sensor, circuit boards.

TUBEHEAD OIL
Inside tubehead

CESIUM IODIDE (CsI)
CCD sensor

For more information on these parts contact your dealer.

# Appendix A. Technical Information

## A.1 Technical specifications

### Type

OP30-1

### Classification

Complies with IEC 60601-1/1995, IEC 60601-2-7/1998, IEC 60601-2-28/1993 and IEC 60601-2-32/1994, IEC 878
UL 2601-11/2006 (for products with the UL Classification Mark) and EN 55011 standards
Conforms with the regulations of DHHS Radiation Performance Standard, 21CFR Subchapter J.
Safety according to IEC 60601-1
Protection against electric shock - Class 1
Degree of protection - Type B applied with no conductive connection to the patient
Protection against the ingress of liquids - IPX 0
Disinfection methods:

- mild soapy water (non-abrasive)
- non-alcohol based disinfectant for the the chin rest
- disposable plastic covers for bite piece, chin rest and lip support

For use in environments where no flammable anaesthetics nor flammable cleaning agents are present
Mode of operation - continuous operation/intermittent loading

### Unit description

A dental panoramic x-ray units with a high frequency switching mode x-ray generator.
The unit takes panoramic exposures.
The unit uses a CCD sensor as an image receptor.

### Generator

TUBE

Toshiba D-052 SB or D-054 SB or equivalent

TUBEHEAD HOUSING ASSEMBLY

THA-M-1

FOCAL SPOT

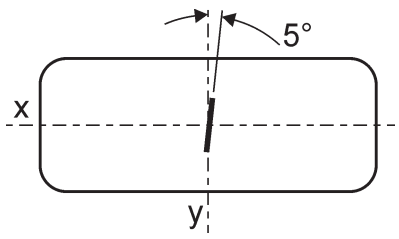
0.5 mm (IEC 60336/1993)

FOCAL SPOT ACCURACY

The accuracy is 10mm from the marking on the tubehead cover

TARGET ANGLE

5º



TARGET MATERIAL
Tungsten
OPERATING TUBE POTENTIAL
**100/115 VAC** pan imaging 66, 70, 73 and 77 kV (±4 kV) at 9mA
**220/230/240 VAC** pan imaging 66, 70, 73 and 77 kV (±4 kV) at 10mA
OPERATING TUBE CURRENT
**100/115 VAC** 9 mA (±1 mA)
**220/230/240 VAC** 10 mA (±1 mA)
NOMINAL ANODE INPUT POWER
**100/115 VAC** 693 W nominal at 77 kV, 9 mA, 10 s
**220/230/240 VAC** 770 W nominal at 77 kV, 10 mA, 10 s
MAXIMUM TUBE CURRENT
**100/115 VAC** 9 mA at 77kVs
**220/230/240 VAC** 10 mA at 77kVs
MAXIMUM ANODE OUTPUT POWER
**100/115 VAC** 693 W, 77 kV, 9 mA, 10 s (110V, 115V)
**220/230/240 VAC** 770 W, 77 kV, 10 mA, 10 s (220V, 230V, 240V)
REFERENCE TIME PRODUCT
**100/115 VAC** 9 mAs at 77 kV
**220/230/240 VAC** 10 mAs at 77 kV
FILTRATION
inherent filtration minimum 0.8 mm Al at 50 kV (IEC 60522/1999)
additional filtration minimum 2 mm Al
patient support attenuation equivalent less than 0.2 mm Al
total fltration minimum 2.8 mm Al at 70 kV
BEAM QUALITY
HVL over 2.77 mm Al at 77 kV
PRIMARY PROTECTIVE SHIELDING
minimum 0.5 mm Pb or equivalent
OUTER SHELL TEMPERATURE
+50ºC (122ºF) maximum
DUTY CYCLE
1:9, controlled by the unit software.
(Example: a 77 kV, 10 mA, 10 s exposure will have a 90 s cool-down period)

## Power requirements

LINE CURRENT
**100 VAC** long term: 1.6 A (cont) 115 VAC mains
momentary: 13.5A at 77 kV/10 mA
**115 VAC** long term: 1.6 A (cont) 115 VAC mains
momentary: 10 A at 77 kV/10 mA
**220/230/240 VAC** long term: 1 A (cont) 230 VAC mains
momentary: 6 A at 77 kV/10 mA, 230 VAC mains

MAXIMUM LINE IMPEDANCE

Maximum apparent resistance of supply mains

**100/115 VAC** 0.4 ohm

**220/230/240 VAC** 0.5 ohm

MAXIMUM LINE FUSING

**100/115 VAC** 16A

**220/230/240 VAC** 10 A

MAIN FUSE

**100/115 VAC** T10A, SPT

**220/230/240 VAC** T6.3 H, SPT

LINE SAFETY SWITCH (when required)

**100/115 VAC** Approved type, min. 16 A 250 VAC

**220/230/240 VAC** Approved type, min. 10 A 250 VAC

EARTH LEAKAGE CIRCUIT BREAKER (when required)

**100/115 VAC** Approved type, min. 16 A 250 VAC

**220/230/240 VAC** Approved type, min. 10 A 250 VAC,
breaker activation leakage current in accordance with local regulations.

## Mechanical parameters

PANORAMIC

Source to Image layer Distance (SID) 500 mm (±10 mm)

Magnification factor 1.25

WEIGHT

120 kg

DIMENSIONS

(H x W x D) 2340 x 835 x 715 mm

VERTICAL HEIGHT OF CHIN REST

950 - 1750 mm (± 10 mm)

## Digital image receptor (CCD)

PIXEL SIZE

96 microns

ACTIVE SENSOR SURFACE

147.5 x 6.1mm

## Timer

EXPOSURE TIMES:

| | |
|---|---|
| Normal | 10.0 s |
| Child | approx. 8.8 s |
| Bitewing | approx. 2.5 + 2.5 s |
| TMJ | approx. 3.1 + 3.1 s |

Accuracy for the displayed exposure times ± 5%

SINGLE LOAD RATING

| | |
|---|---|
| **100/115 VAC** | 77 kV, 9 mA, 10 s, panoramic |
| **220/230/240 VAC** | 77 kV, 10 mA, 10 s, panoramic |

BACK-UP TIMER

12 s (±15%)

## Leakage technique factors

PANORAMIC

| | |
|---|---|
| **100/115 VAC** | 3240 mAs/h, exposure with maximum values (77 kV, 9 mA, 10 s) |
| **220/230/240 VAC** | 3600 mAs/h, exposure with maximum values (77 kV, 10 mA, 10 s) according to the 1:9 duty cycle |

## Measurement bases

The kV is measured by monitoring differentially the current flowing through 450 Mohm, 1% feedback resistor connected between the tube anode and ground.
The mA is measured by monitoring current in the HT return line, which equals the tube current.

## Collimator

TYPE

BLD-M-1

PRIMARY SLIT

Adult panoramic slit only. For child panoramic the exposure time is reduced to give a reduced length image.

PRIMARY SLIT SIZE

0.7 - 0.75 x 38 mm

## Z-motor

DUTY-CYCLE

-Intermediate use: 6.25%, 25s ON, 400s OFF

## Environmental data

OPERATING

- Ambient temperature from +10ºC to +40ºC
- Relative humidity 10 - 90%, no condensation

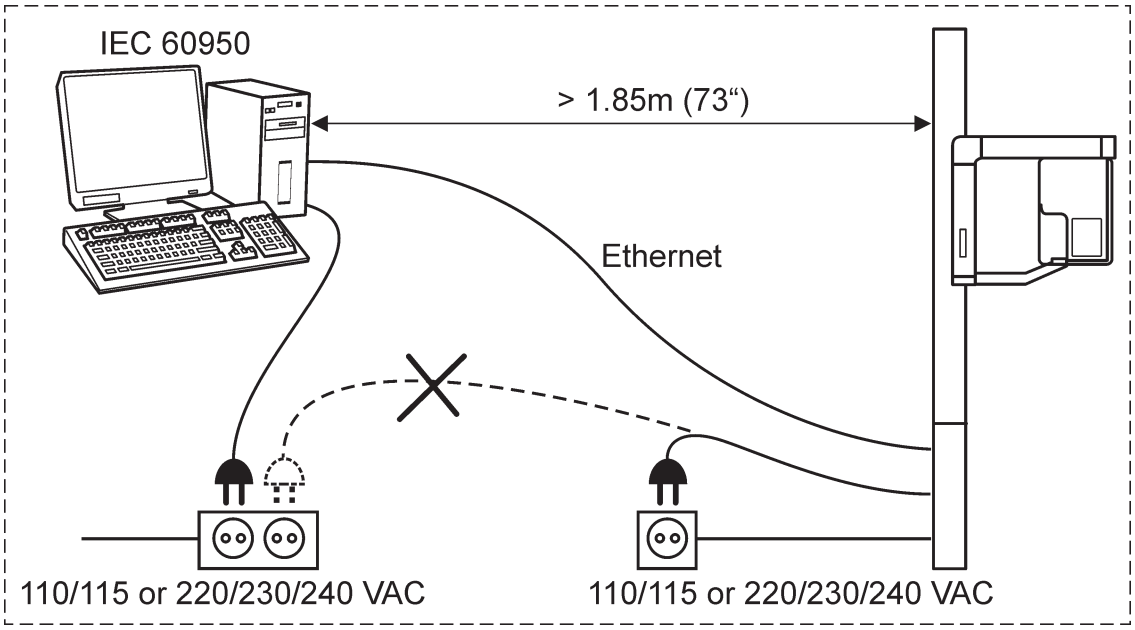
STORAGE/TRANSPORTATION

- Ambient temperature from -20ºC to +50ºC
- Relative humidity 5 - 85% no condensation
- Atmospheric pressure 500 - 1080 mbar

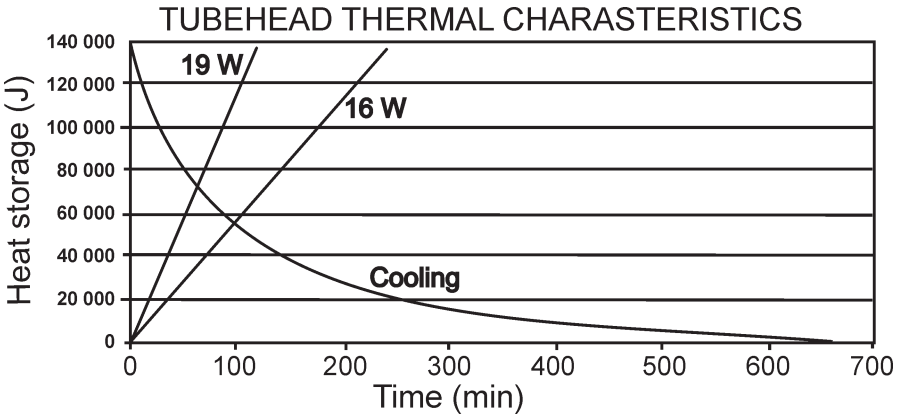
## System requirements and connections

- The PC and any other external device(s) connected to the system must meet the IEC 60950 standard (minimum requirements). Devices that do not meet the IEC 60950 standard must not be connected to the system as they may pose a threat to operational safety.
- The PC and any other external devices must be connected in accordance with IEC 60601-1-1.
- The x-ray unit must be connected to it's own separate power supply. The PC and any other external devices must NOT be connected to the same power supply as the x-ray unit.
- Position the PC and any other external device at least 1.85 m (73") from the x-ray unit so that the patient cannot touch the PC or any other external device while being x-rayed.
- The PC and any other external devices shall not be connected to an extension cable.
- Multiple extension cables shall not be used.
- Do not position the PC where it could be splashed with liquids.
- Clean the PC in accordance with the manufacturer's instructions.

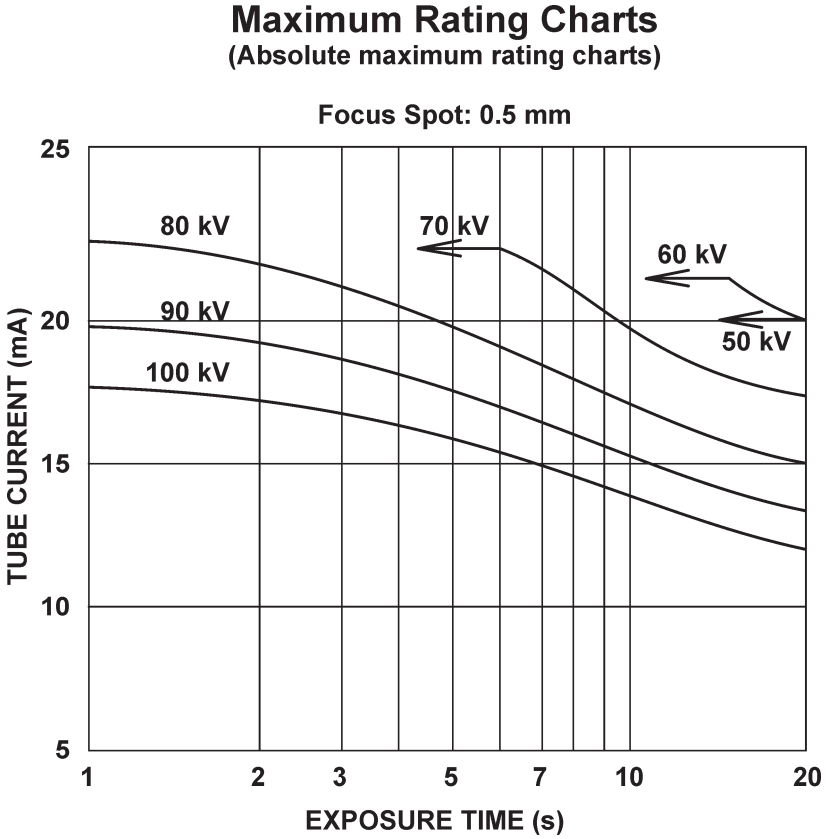
## X-ray system - to IEC 60601-1-1



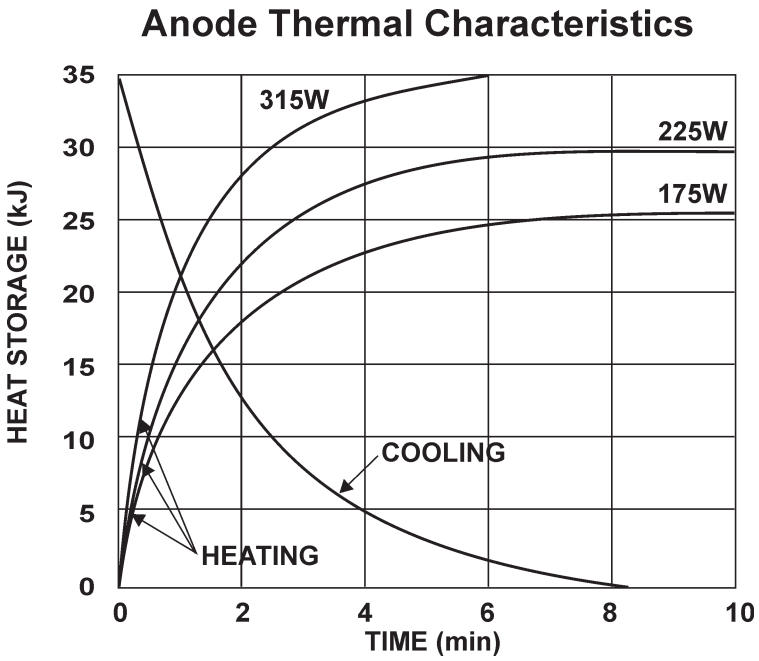
## Tube housing assembly cooling/heating characteristics



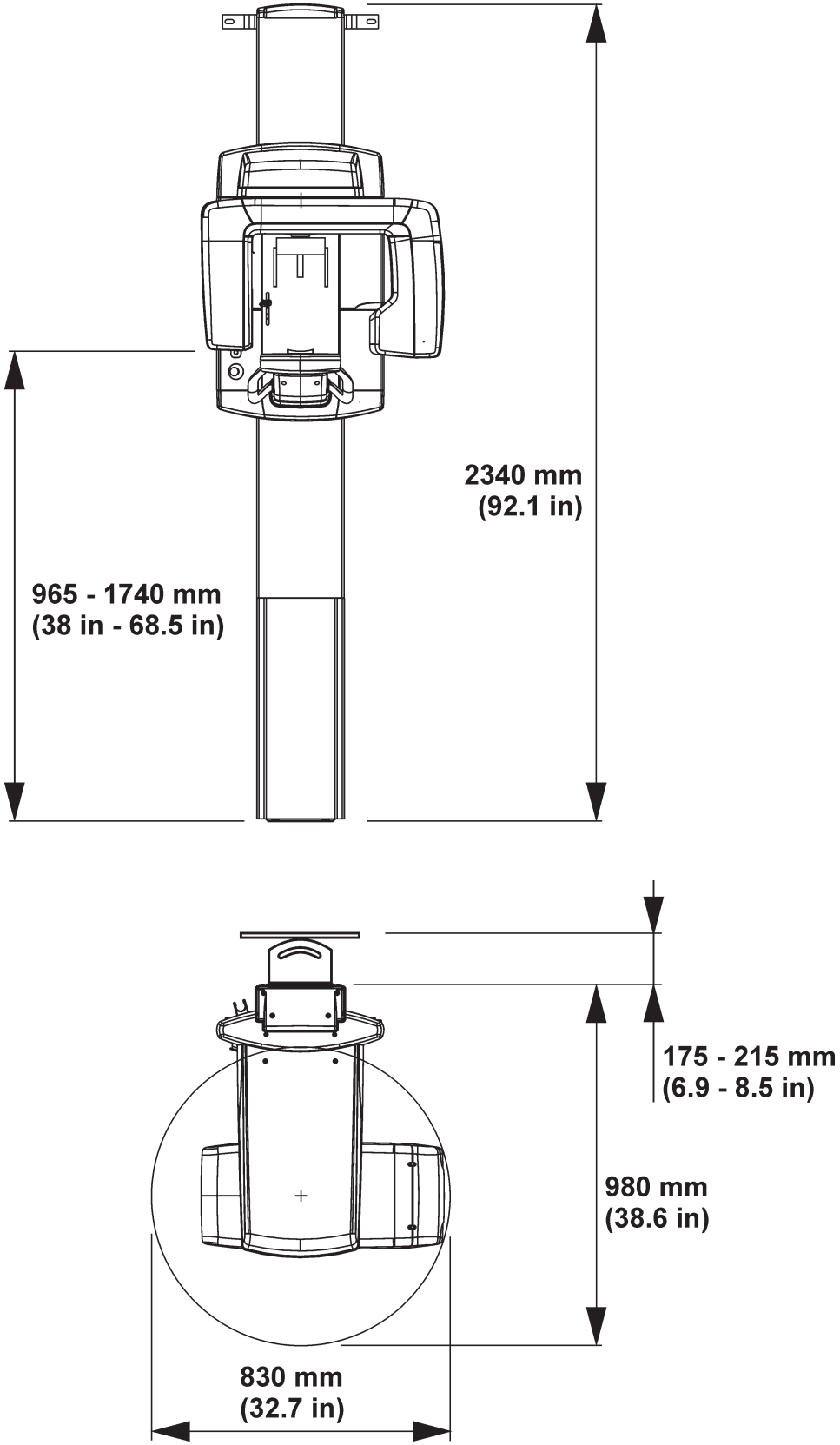

## Tube rating chart Toshiba D-052 SB



## Anode thermal characteristics



## A.2 Unit dimensions



## A.3 Symbols that appear on the unit

Radiation warning

Dangerous voltage

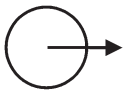

On or enabled

Off or disabled

Exposure switch

Connector for Ethernet RJ45

Connector for exposure switch


Connector for external exposure light

Attention, consult accompanying documents

Ground (Functional)

Protective ground

CLASS 1 LASER PRODUCT

EN 60 825-1/A2:2001

Laser class label
(Patient positioning lights)

This symbol indicates that the waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.

Type B equipment

CE 0537

CE (0537) symbol
MDD 93/42/EEC

ETL symbol

CH01

## A.4 EMC declaration

| Guidance and manufacturer's declaration – electromagnetic emissions | | |
|---|---|---|
| The OP30-1 is intended for use in the electromagnetic environment specified below. The customer or the user of the OP30-1 should assure that it is used in such an environment. | | |
| **Emissions test** | **Compliance** | **Electromagnetic environment - guidance** |
| RF emissions CISPR 11 | Group 1 | The OP30-1 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF emissions CISPR 11 | Class B | The OP30-1 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic emissions IEC 61000-3-2 | Class A | |
| Voltage fluctuations/ flicker emissions IEC 61000-3-3 | Complies | |

| **Guidance and manufacturer's declaration – electromagnetic immunity** | | | |
|---|---|---|---|
| The OP30-1 is intended for use in the electromagnetic environment specified below. The customer or the user of the OP30-1 should assure that it is used in such an environment. | | | |
| Immunity test | IEC 60601 test level | Compliance level | Electromagnetic environment - guidance |
| Electrostatic discharge (ESD) IEC 61000-4-2 | ±6 kV contact<br><br>±8 kV air | ±6 kV contact<br><br>±8 kV air | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %. |
| Electrical fast transients/bursts IEC 61000-4-4 | ±2 kV for power supply lines<br>±1 kV for input/output lines | ±2 kV for power supply lines<br>±1 kV for input/output lines | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge IEC 61000-4-5 | ±1 kV differential mode<br>±2 kV common mode | ±1 kV differential mode<br>±2 kV common mode | Mains power quality should be that of a typical commercial or hospital environment. |
| Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11 | <5 % $U_T$<br>(>95 % dip in $U_T$)<br>for 0.5 cycle<br><br>40 % $U_T$<br>(60 % dip in $U_T$)<br>for 5 cycles<br><br>70 % $U_T$<br>(30 % dip in $U_T$)<br>for 25 cycles<br><br><5 % $U_T$<br>(>95 % dip in $U_T$)<br>for 5 sec | <5 % $U_T$<br>(>95 % dip in $U_T$)<br>for 0.5 cycle<br><br>40 % $U_T$<br>(60 % dip in $U_T$)<br>for 5 cycles<br><br>70 % $U_T$<br>(30 % dip in $U_T$)<br>for 25 cycles<br><br><5 % $U_T$<br>(>95 % dip in $U_T$)<br>for 5 sec | Mains power quality should be that of a typical commercial or hospital environment. If user of the OP30-1 requires continued operation during power mains interruptions, it is recommended that the OP30-1 be powered from an uninterruptible power supply or a battery. |
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 3 A/m | 3 A/m | Power frequency magnetic field should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| NOTE $U_T$ is the ac. mains voltage prior to application of the test level. | | | |

<table>
<tr><th colspan="4">Guidance and manufacturer's declaration – electromagnetic immunity</th></tr>
<tr><td colspan="4">The OP30-1 is intended for use in the electromagnetic environment specified below. The customer or the user of the OP30-1 should assure that it is used in such an environment.</td></tr>
<tr><td>Immunity test</td><td>IEC 60601 test level</td><td>Compliance level</td><td>Electromagnetic environment - guidance</td></tr>
<tr><td>Conducted RF<br>IEC 61000-4-6</td><td>3 Vrms<br>150 kHz to<br>80 MHz</td><td>3 V</td><td rowspan="2">Portable and mobile RF communications equipment should be used no closer to any part of the OP30-1, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br><br>Recommended separation distance<br>$d = 1.2\sqrt{P}$<br><br>$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz<br><br>$d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz<br><br>where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and $d$ is the recommended separation distance in metres (m).<br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a] , should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol:<br><br> </td></tr>
<tr><td>Radiated RF<br>IEC 61000-4-3</td><td>3 V/m<br>80 MHz to<br>2.5 GHz</td><td>3 V/m</td></tr>
<tr><td colspan="4">NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.<br>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</td></tr>
<tr><td colspan="4">[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicated theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the OP30-1 is used exceeds the applicable RF compliance level above, the OP30-1 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting of relocating the OP30-1.<br>[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</td></tr>
</table>

**Recommended separation distances between portable and mobile RF communications equipment and the OP30-1.**

The OP30-1 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the OP30-1 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the OP30-1 as recommended below, according to the maximum output power of the communications equipment.

| Rated maximum output power of transmitter W | Separation distance according to frequency of transmitter m | | |
|---|---|---|---|
| | 150 kHz to 80 MHz $d = 1.2\sqrt{P}$ | 80 MHz to 800 MHz $d = 1.2\sqrt{P}$ | 800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$ |
| 0.01 | 0.12 | 0.12 | 0.23 |
| 0.1 | 0.38 | 0.38 | 0.73 |
| 1 | 1.2 | 1.2 | 2.3 |
| 10 | 3.8 | 3.8 | 7.3 |
| 100 | 12 | 12 | 23 |

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1. At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.